UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RICHARD WISNEIEWSKI
And LEONIDAS C. LEONARD

Appeal 2007-0867
Application 09/895,936
Technology Center 3700

Decided: April 30, 2007

Before EDWARD C. KIMLIN, BRADLEY R. GARRIS, and CHUNG K. PAK, *Administrative Patent Judges*.

KIMLIN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 88, 89, 96, 101, 105-116, 118, and 119. Claims 69-87, 90-95, 97-100, 102-104, and 120-123 have been withdrawn from consideration. Claim 88 is illustrative:

88. A method of processing a biopharmaceutical product comprising:

providing a vessel adapted to receive a medium comprising a biopharmaceutical product therein, said vessel having an interior cavity defined by an interior wall of said vessel and a heat exchange structure within said cavity, said heat exchange structure having one or more heat transfer members;

placing a medium comprising a biopharmaceutical product within said vessel;

activity cooling said interior wall using a cooling fluid; and

forming a thermal bridge within a gap between said heat transfer members and said interior wall by said medium wherein heat is transferred from said heat transfer member through said thermal bridge to said interior wall.

The Examiner relies upon the following references in the rejection of the appealed claims:

Voorhees	US 983,466	Feb. 7, 1911
Morrison	US 1,874,578	Aug. 30, 1932
West	US 2,114,642	Apr. 19, 1938
Finnegan	US 2,129,572	Sep. 6, 1938
Brown	US 2,391,876	Jan. 1, 1946
Gross	US 2,915,292	Dec. 1, 1959
Burroughs	US 3,318,105	May 9, 1967
Euwema	US 3,550,393	Dec. 29, 1970
Nakao (as translated)	JP 57-58087	Apr. 7, 1982

Kalhori, "Studies on Heat Transfer From a Vertical Cylinder, With or Without Fins, Embedded in a Solid Phase Change Medium," *Transactions of the ASME, Journal of Heat Transfer,* Vol. 107, 44-51 (Feb. 1985).

Wisniewski, "Large-Scale Freezing and Thawing of Biopharmaceutical Drug Product," *Proceedings of the International Congress*, Advanced Technologies For Manufacturing of Aseptic & Terminally Sterilized Pharmaceuticals & Biopharmaceuticals, 132-139 (Feb. 1992).

Cothern US 5,535,598 Jul. 16, 1996

The present application is closely related to Appellants' co-pending application, U.S. Serial No. 09/881,909, filed June 15, 2001. The co-pending application is presently before us on appeal (Appeal No. 2006-3326). The prior art applied by the Examiner in the present appeal has also been applied against the claims in the co-pending appeal. The claims of the instant appeal are directed to a method of processing a biopharmaceutical product using a thermal transfer system wherein a thermal bridge is formed within a gap between heat transfer members located within a vessel and the interior wall of the vessel. The claims of the co-pending appeal are directed to the thermal transfer system, in general.

The Examiner has withdrawn the rejection of the appealed claims under 35 U.S.C. § 112, second paragraph. Appealed claims 88, 89, 96, 105, 108-110, 112-115, 118, and 119 stand rejected under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Wisniewski. The appealed claims also stand rejected under 35 U.S.C. § 103(a) as follows:

> (a) claims 88, 89, 96, 105, 108-110, 112-115, 118, and 119 over Wisniewski in view of Euwema, Cothern, Kalhori, Morrison, and Nakao,
>
> (b) claims 96, 105-110, 112-115, 118, and 119 over Wisniewski in view of Kalhori,

(c) claims 96, 105-110, 112-115, 118, and 119 over Wisniewski in view of Kalhori, Euwema, Cothern, West, Morrison, and Nakao,

(d) claims 96, 105-110, 112-115, 118, and 119 over the prior art cited in (c) above in view of the admitted prior art, and

(e) claims 101, 111, and 116 over the prior art cited in (a) above further in view of Gross or Brown.

Appellants have not contested the Examiner's determination that claims 88, 89, 96, 105-110, 112-116, 118, and 119 stand or fall together, as do claims 101 and 111 (*see* page 3 of Answer, penultimate para.).

We have thoroughly reviewed each of Appellants' arguments for patentability, as well as the Declaration Evidence relied upon in support thereof. However, for the reasons set forth in our decision in the co-pending appeal noted above (Appeal No. 2006-3326), and the reasons well stated by the Examiner in the Answer and the Final Rejection, we find that the Examiner's rejections are well founded and in accord with current patent jurisprudence. Accordingly, we will sustain the Examiner's rejections.

A principal argument advanced by Appellants is that the thermal transfer system of Wisniewski for processing a biopharmaceutical product does not allow for the formation of a thermal bridge between the heat transfer members and the interior wall of the container or vessel. However, as explained in our decision in the co-pending appeal, we find that the Examiner has effectively made out a prima facie case of inherency to shift to Appellants the burden of establishing on this record that the Wisniewski system, or one closely related thereto, is not capable of forming a thermal bridge within the scope of the appealed claims. In our view, the Wisniewski

Declarations proffered by Appellants present an opinion that is without the requisite factual support to rebut the Examiner's reasonable analysis. Both Appellants and the Examiner seem to agree that an analysis of the heat transfer in a system like Wisniewski and the one presently claimed is quite complex and requires actual experimentation or sophisticated computer simulation. However, there is no evidence of record that Appellants performed such an analyses to support their conclusion that the thermal transfer system of Wisniewski is not capable of providing the claimed thermal bridge. We note that every opinion offered in the Wisniewski declarations is prefaced by the reservation "to the best of my knowledge."

We also find, for the reasons set forth in our decision in the co-pending appeal, that the prior art of record supports the Examiner's legal conclusion that it would have been obvious for one of ordinary skill in the art to extend the heat exchange fins of Wisniewski in closer proximity to the wall of the container in order to improve heat transfer. Appellants have presented no evidence of unexpected results associated with the heat exchange structure being closer to the container wall than is disclosed by Wisniewski. We are not persuaded by Appellants' argument that not all of the prior art cited by the Examiner is directed to processing biopharmaceutical products. We agree with the Examiner that the basic principles of heat transfer in a liquid medium remain the same whether the medium is a biopharmaceutical product or an inorganic solution. Appellants have not demonstrated that anything more than routine experimentation was used to formulate the claimed method on appeal.

We again note that Appellants' Specification discloses that the size of the gap filled by the thermal transport bridge "can be determined through simple trial and error, and the optimum gap may be *no gap*" (page 6 of Specification, lines 12-14, emphasis added). Hence, there does not appear to be a structural distinction between the thermal transfer systems of the admitted prior art, wherein the heat exchange structures are connected to the interior wall of the container, and heat transfers systems within the scope of the appealed claims where no gap between the heat exchange structure and the container wall is the "optimum gap."

In conclusion, based on the foregoing, the Examiner's decision rejecting the appealed claims is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(iv)(effective Sept. 13, 2004).

AFFIRMED

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